CLAIMS

1. A lyophilized composition of TFPI or TFPI variant comprising (1) TFPI or TFPI variant and (2) a carbohydrate or amino acid glass forming agent, wherein the lyophilized composition has about 45% or greater aggregation stability.

2. The lyophilized composition of claim 1 which comprises TFPI variant wherein the TFPI variant is at least about 70% or more homologous to TFPI (SEQ ID NO:1).

3. The lyophilized composition of claim 2 wherein the TFPI variant is ala-TFPI.

4. The lyophilized composition of claim 1 wherein the glass forming agent is selected from the group consisting of a monosaccharide, a disaccharide, a trisaccharide, a naturally occurring amino acid, and combinations thereof.

5. The lyophilized composition of claim 1 which has an aggregation stability in a range selected from the group consisting of aggregation stabilities of about 45% or greater to about 95% or greater, about 70% or greater to about 95% or greater, and about 85 or greater to about 96% or greater.

6. The lyophilized composition of claim 1 which has an aggregation stability in a range of about 45% or greater to about 96% or greater.

7. A lyophilized composition of TFPI or TFPI variant, wherein before lyophilization the TFPI or TFPI variant is present in an aqueous formulation comprising a carbohydrate or amino acid glass forming agent, wherein the aqueous formulation has a pH of about 4 to about 8.

8. The composition of claim 7 wherein the aqueous formulation comprises about 50 mM to about 600 mM of the glass forming agent.

9. The composition of claim 7 wherein the aqueous formulation further comprises about 5 mM to about 600 mM of a buffer.

10. The composition of claim 9 wherein the buffer is selected from the group consisting of phosphate, succinate, glutamate, imidazole, citrate, histidine, glycine, arginine, and combinations thereof.

11. The composition of claim 7 wherein the pH of the aqueous formulation is about 5.5 to about 6.5.

12. The composition of claim 7 wherein the aqueous formulation comprises a concentration of TFPI or TFPI variant selected from the group of concentrations consisting of:

no more than about 10 mg/ml of the TFPI or TFPI variant;

no more than about 1 mg/ml of the TFPI or TFPI variant; and

no more than about 0.2 mg/ml of the TFPI or TFPI variant.

13. The composition of claim 7 wherein the aqueous formulation is selected from the group of formulations consisting of:

about 300 mM arginine and about 20 mM sodium citrate, with a pH of about 5.5;

about 3% (w/v) arginine and about 10 mM sodium citrate, with a pH of about 6;

about 2% (w/v) lysine and about 10 mM sodium citrate, with a pH of about 6;

about 8.5% (w/v) sucrose, about 0.1% (w/v) polyphosphate, and about 10 mM sodium citrate, with a pH of about 6;

about 8.5% (w/v) sucrose and about 10 mM histidine, with a pH of about 6; and

about 8.5% (w/v) sucrose and about 10 mM imidazole, with a pH of about 6.5.

14. The composition of claim 7 wherein the aqueous formulation further comprises a crystal forming agent.

15. The composition of claim 14 wherein the crystal forming agent is selected from the group consisting of mannitol, alanine, glycine, NaCl, and combinations thereof.

16. The composition of claim 14 wherein the aqueous formulation comprises about 0.5% (w/v) to about 16% (w/v) of the crystal forming agent.

17. The composition of claim 14 wherein the aqueous formulation is selected from the group of formulations consisting of:

about 3% (w/v) arginine, about 4% (w/v) mannitol, and about 10 mM sodium citrate, with a pH of about 6;

about 3% (w/v) arginine, about 2% (w/v) glycine, and about 10 mM sodium citrate, with a pH of about 6;

about 3% (w/v) arginine, about 4% (w/v) mannitol, and about 10 mM sodium citrate, with a pH of about 6;

about 1% (w/v) sucrose, about 4% (w/v) mannitol, and about 10 mM L-histidine, with a pH of about 6;

about 1% (w/v) sucrose, about 2% (w/v) glycine, and about 10 mM histidine, with a pH of about 6;

about 1% (w/v) sucrose, about 4% (w/v) mannitol, and about 10 mM imidazole, with a pH of about 6.5; and

about 1% (w/v) sucrose, about 2% (w/v) glycine, and about 10 mM imidazole, with a pH of about 6.5.

18. A lyophilized composition of TFPI or TFPI variant comprising (1) TFPI or TFPI variant and (2) a citrate buffer, wherein the lyophilized composition has about 45% or greater aggregation stability.

19. The lyophilized composition of claim 18 which has an aggregation stability in a range of about 45% or greater to about 96% or greater.

20. A lyophilized composition of TFPI or TFPI variant comprising (1) TFPI or TFPI variant, (2) sulfate, and (3) a phosphate buffer, wherein the lyophilized composition has about 45% or greater aggregation stability.

21. The lyophilized composition of claim 20 which has an aggregation stability in a range of about 45% or greater to about 96% or greater.